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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,029	07/24/2001	Gabor Bogye	21965	6045

535 7590 10/11/2005

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,029	BOGYE, GABOR	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-13,15,16 and 19-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-13, 15-16, and 19-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In view of the Appeal Brief filed on July 19, 2005, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Upon reconsideration, the outstanding rejection under 35 USC 112, first paragraph is withdrawn in view of the applicant's remarks filed July 19, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-21, 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "an otherwise healthy patient" recited in claims 19-21, 23, and 24 renders the claims indefinite as to the patient population encompassed thereby. It is not clear what patients or individually would be considered "healthy" as recited in the claims. Is patients experiencing side effect from the medication considered "healthy"? For example, if a patient takes progesterone composition and experience headache or depression after taking the medication, is she a "healthy" patient? The metes and bounds of the claims are not clear. Furthermore, are they otherwise healthy if no medication was taken (including the hormonal composition)? Or does the term mean that the patients are healthy if no plasma homocysteine reducing agents are taken?

Examiner notes that the term "otherwise healthy patient" is interpreted as individual who is healthy without taking the hormonal composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9-13, 15-16, 21, 22, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by the abstract of Ali et al. (Preventive Medicine, 1995;24(5):528-534) as evidenced by USDA Nutrient Database, Release 12, 1998, Monograph No. 01077). Both references are of record.

Ali et al. teaches elderly women taking HRT (Hormone Replacement Therapy) and at the same time drinking milk (See the abstract), with majority of patients noted consistent comsumption of the reported amount of milk throughout their lives (See page 531, col. 1).

Since milk containing vitamin B6, B12, and folic acid (See USDA Nutrient Database 01077), the method of women taking both HRT and milk taught in Ali would read on the herein claimed method (See *Ex parte Novitski*,26 USPQ2d 1389 (BOPA 1993), *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989), and *In re Winkhaus*, 52 F.2d 637, 188 USPA 219 (CCPA 1975) and explanation below).

Claims 19, 20, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Spellacy et al. (Contraception, 1972;6(4):263-273), reference of record.

Spellacy et al. teaches vitamin B6 supplement is administered to women taking progesterone containing oral contraceptive (See the abstract).

Claims 19, 20, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Butterworth et al. (Am. J. Clin. Nutr., 1982;35(1):73-82 from IDS received 1/2/2002).

Butterworth et al. teaches folic acid was supplemented to women taking progesterone containing oral contraceptive (See the abstract).

Claims 9-11, 13, 15-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Kafrissen et al. (US Patent 6,190,693).

Kafrissen et al. teaches a method of administering folic acid along with either oral contraceptives containing progesterone or hormone replacement therapy containing progesterone (See for example claims 5 and 8). Kafrissen et al. also teaches the amount of folic acid employed as 25microgram to 1gram to reducing homocyteine level (See col. 7, lines 55-56).

Response to arguments

Applicant's arguments filed July 19, 2005 averring Ali's failure to teach or suggest the invention have been considered, but are not found persuasive. Examiner notes that the method of women taking both HRT and milk taught in Ali would read on the herein claimed method (See *Ex parte Novitski*,26 USPQ2d 1389 (BOPA 1993), *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989), and *In re Winkhaus*, 52 F.2d 637, 188 USPA 219 (CCPA 1975)) because of the risk-reduction properties is considered

inherently present in the folic acid, vitamin B6 and B12 regardless of what the purpose of milk consumption might be.

Applicant's arguments filed July 19, 2005 averring Ali's failure to teach the effective amount have been considered, but are not found persuasive. Examiner notes that the disclosure in the specification is a general reference. In page 6 of the instant specification states, "the effective dosage is generally in the range of from 100 microgram to 9 gram per day of plasma homocysteine content reducing agents". Exxaminer notes that no particular amounts are excluded from such disclosure. In other words, the effective amount is an open-end definition. Given a broadest interpretation to the limitations recited in the claims, any amount would be "effective amount" for reducing the risk to the patient of thromboembolism.

Applicant's arguments filed July 19, 2005 averring the cited prior art's failure to teach "otherwise healthy patients" have been considered, but are not found persuasive. As stated above, the term "otherwise healthy patients" is construed as individual who is healthy without taking the hormonal composition. And in the instant case, they are presumably healthy prior to the administration of the hormonal composition. Furthermore, not all the patients in Spellacy reference experiencing the "disturbed glucose metabolism". For example, patient 10 is normal in the glucose tolerance test even she is taking oral contraceptive (See page 268, Table I of Spellacy).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-13, 15-16, and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (US Patent 5,654,011) in view of Fermo et al. (Annals of Internal Medicine, 1995:123(10):747-753 – html version).

Jackson et al. teaches a multivitamin composition containing homocysteine level reduction amount of folic acid, vitamin B6, and vitamin B12 (See col. 3, line 60-63, col. 5, lines 15-30, col. 6, lines 18-21). Jackson's composition is taught as useful inn various stages of women life for reducing health risks of women (See the abstract).

Jackson et al. does not expressly teach the patients taking hormonal composition containing gestagen.

Fermo et al. teaches hyperhomocysteinemia as pathogenic significant of patients developing thrombosis (See the abstract and the Discussion Section).

It would have been obvious to one of ordinary skill in the art at the time of invention to employ folic acid, vitamin B6, and vitamin B12 to reduce the serum level of homocysteine and thereby the risk of coronary disease in patients taking gestagen composition.

One of ordinary skill in the art would have been motivated to employ folic acid, vitamin B6, and vitamin B12 to reduce the serum level of homocysteine and thereby the risk of coronary disease in patients taking gestagen composition. It is known that high homocysteine level is associated with coronary diseases including thrombosis. Therefore, employing a homocysteine reducing amount of vitamin B6, B12, and folic acid, regardless of what the cause of hyperhomocysteinemia or patient population might be, to any patient suffering from hypercysteinemia including patient population herein recited, would be reasonably expected to be useful and effective in lowering the homocysteine level and further reducing the risk of thrombosis thereby.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Primary Examiner
Art Unit 1617

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER